

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on July 25, 2008, has been entered.

1. Claims 1-4 are pending in the application<sup>1</sup>.

### ***Information Disclosure Statement***

2. The information disclosures filed July 25, 2008, August 5, 2008, and August 14, 2008, have been considered. An initialed copy of each is enclosed.

### ***Response to Amendment***

3. The amendment filed on July 25, 2008, is considered non-compliant because it fails to meet the requirements of 37 CFR § 1.121, as amended on June 30, 2003 (see *68 Fed. Reg. 38611*, Jun. 30, 2003). However, in order to advance prosecution<sup>2</sup>, rather than mailing a Notice of Non-Compliant Amendment, Applicant is advised of the following deficiency, which is corrected by the Examiner's Amendment to the Claims that follows.

The amendment filed on July 25, 2008, is non-compliant because it fails to show each and every change made relative to the immediate prior version thereof, though it

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<sup>1</sup> Claims originally presented as claims 1, 6, 7, and 10 were previously allowed and renumbered as claimed 1-4, respectively; see the Notice of Allowance mailed April 25, 2008.

<sup>2</sup> See M.P.E.P. § 714.03.

may be apparent that Applicant did not intend to amend claim 10 to read, "if claim 6", rather than "of claim 6".

Additionally, the amendment filed July 25, 2008, sets forth improperly numbered claims since the claims presented were renumbered as claims 1-4 by the Office action mailed April 25, 2008.

The amendment filed on July 25, 2008, has not been entered.

4. For clarity, the following is a listing of the claims now pending in this application<sup>3</sup>:

Claim 1. (Previously Presented) A peptide consisting of the amino acid sequence of SEQ ID NO: 2.

Claim 2. (Previously Presented) A composition comprising the peptide of claim 1.

Claim 3. (Currently Amended) The composition of claim [[6]] 2, further comprising a pharmaceutically acceptable carrier or diluent.

Claim 4. (Currently Amended) The composition of claim [[6]] 2, characterized in that it further comprises one or more compounds selected from the group consisting of an adjuvant, one or more cytokines, antibodies directed against CD2, CD3, CD27, CD28 or other T cell surface antigens, and helper epitopes to stimulate CD4+ or CD8+ T cells.

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<sup>3</sup> The dependency of claims 3 and 4 has been changed, so as to be consistent with the numbering of the claims following their renumbering by the preceding Office action mailed April 25, 2008.

***Allowable Subject Matter***

5. The indicated allowability of claims 1-4 is withdrawn in view of U.S. Patent No. 5,844,075-A, which teaches a peptide consisting of an amino acid sequence that is identical to the amino acid sequence set forth in this application as SEQ ID NO: 2.

A rejection based on this reference follows.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,844,075-A (of record; cited by Applicant).

U.S. Patent No. 5,844,075-A (Kawakami et al.) teaches a peptide consisting of an amino acid sequence that is identical to the amino acid sequence of SEQ ID NO: 2, as set forth in this application; see entire document (e.g., column 24, line 66, through column 25, line 28). Kawakami et al. teaches compositions comprising the disclosed peptide, which further comprise pharmaceutically acceptable carriers and/or adjuvants; see, e.g., column 16, lines 9-23; and column 26, lines 24-64. Furthermore, Kawakami et al. teaches the compositions are administered to a subject in conjunction or combination with cytokines; see, e.g., column 18, lines 25-32.

***Conclusion***

8. No claim is allowed.

9. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. Kawakami et al. (U.S. Patent Application Publication No. 2003/0144482-A1) (of record; cited by Applicant) teaches a variant of the naturally occurring peptide of SEQ ID NO: 9, which differs from the naturally occurring peptide by substitution of the threonine residue at position 2 of the sequence by valine (i.e., a variant consisting of the amino acid sequence of SEQ ID NO: 2, as disclosed in the instant application).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stephen L. Rawlings/

Stephen L. Rawlings, Ph.D.  
Primary Examiner, Art Unit 1643

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September 15, 2008